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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,192	07/03/2006	Shigeru Kabayama	0033-1084PUS1	6174

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EXAMINER
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ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1616

NOTIFICATION DATE	DELIVERY MODE
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04/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,192	<b>Applicant(s)</b> KABAYAMA ET AL.	
	<b>Examiner</b> ERNST V. ARNOLD	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/3/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/21/09 has been entered.

Claims 2 and 9-15 have been cancelled. Claims 1 and 3-8 are under examination.

#### **Withdrawn rejections:**

Applicant's amendments and arguments filed 1/21/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-8 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Cantoro (EP 0698388 A1).

Cantoro discloses artificial tear salt solutions with a **pH of between 6.8 and 7.6** and an osmotic pressure of **140-280 mOsm/L** comprising 40 mmol/L sodium, 12 mmol/L potassium and 50 mmol/L chloride (claims 1-12). In the absence of evidence to the contrary, these amounts read on the amounts in instant claims 4-6. Cantoro clearly teaches on page 4, lines 45-53 various concentration of K<sup>+</sup> and Na<sup>+</sup> that can be used in the invention.

Na <sup>+</sup>	40-95 mmol/l	Cl <sup>-</sup>	50-150 mmol/l
K <sup>+</sup>	12-28 mmol/l	HPO <sub>4</sub> <sup>-</sup>	7-20 mmol/l
Ca <sup>++</sup>	0.4-1.5 mmol/l	citrate	0.7-2.5 mmol/l
Mg <sup>++</sup>	0.4-1.0 mmol/l	hyaluronate	0.05-2% by weight

While Cantoro does not disclose a hydrogen reactive value of 0.01-1 or the oxidation reduction potential of between -800 to +200 mV such features are deemed inherent in the composition since all of the components are within the instantly claimed amounts and the fact that the USPTO does not have the analytical equipment necessary to measure physical properties that were previously unmeasured in the art. The burden is the appropriately shifted to Applicant to demonstrate a difference between the prior art and the instantly claimed invention. With respect to the limitation that the ion balance is carried out on electrolytic reduction of water it is the Examiner's position that the prior art product is the same as the instant product in the absence of evidence to the

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contrary. Please note that in product-by-process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference.” MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the “patentability of a product does not depend on its method of production.” In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, **used as a cleaning solution for eyes or the nose**, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

**Response to arguments:**

Applicant asserts that the reference does not teach the intended use but the intended use is inherent in the composition as discussed above.

***Claim Rejections - 35 USC § 102***

Claims 1, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoshino et al. (JP2000-157977; IDS filed on 7/3/06).

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Hoshino et al. disclose in the English language Abstract an electrolytic water without stimulating or denaturing cells and having high sterilizing power in the electrolytic water generated by electrolyzing a water to be electrolyzed containing, an osmotic pressure regulating substance by specifying the osmotic pressure of the electrolytic water. Hoshino et al. teach how to make the electrolytic water: the electrolytic water is generated by electrolyzing water to be electrolyzed in an electrolytic cell, and the osmotic pressure is set at 128-322 mOsm. At this time, the water to be electrolyzed is the mixed solution of at least one between a chloride such as sodium chloride and a pH regulator such as hydrochloric acid and water. The electrolytic water is preferably kept at a pH of 3-8.5, and the chlorine concentration, of the electrolytic water is preferably controlled to 1-150 ppm. Further, the sodium chloride concentration, is set at 0.4-1.0%. Thus, Hoshino et al. fairly disclose an artificial salt solution with a pH of 3-8.5 and an osmotic pressure of 128-322 mOsm made by electrolyzing water and anticipating instant claims 1, 7, and 8.

While Hoshino et al. do not disclose a hydrogen reactive value of 0.01-1 or the oxidation reduction potential of between -800 to +200 mV such features are deemed inherent in the composition since all of the components are within the instantly claimed amounts and the fact that the USPTO does not have the analytical equipment necessary to measure physical properties that were previously unmeasured in the art. The burden is the appropriately shifted to Applicant to demonstrate a difference between the prior art and the instantly claimed invention.

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With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, **used as a cleaning solution for eyes or the nose**, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

**Response to arguments:**

Since the arguments are the same as above, the Examiner's rebuttal is the same as above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morisawa et al. (EP 0826636; IDS filed on 1/28/08) in view of Cantoro (EP 0698388 A1) and Hoshino et al. (JP2000-157977).

Applicant claims an artificial salt solution.

### **Determination of the scope and content of the prior art**

#### **(MPEP 2141.01)**

Morisawa et al. teaches in claim 9:

**A method of producing electrolytic hydrogen dissolved water comprising the steps of:**

**preparing raw water including at least sodium, potassium, magnesium and calcium ions,  
obtaining purified water from said raw water,  
adding a catalyst for promoting electrolysis in said purified water, and  
electrolyzing said purified water added with said catalyst, and then deriving cathode water.**

Morisawa et al. teach that the catalyst is NaCl (see figure 1). Morisawa et al. teach that the electrolytic water has dissolved hydrogen of at least 0.1 ppm and the solution is *neutralized* which means it has a pH of about 7.0 (claims 1 and 2). The hydrogen reactive value is intrinsic to the composition of Morisawa et al. since it has dissolved hydrogen present. Morisawa et al. teach that the ox-red potential is not more than +100 mV (claim 6). Morisawa et al. teach a wide variety of applications for the solution including transfusion formulation, dialysis treatment solution, peritoneal dialysis solution, or medicine (claim 8).



The references of Cantoro and Hoshino are discussed in detail above and those discussions are hereby incorporated by reference.

**Ascertainment of the difference between the prior art and the claims**

**(MPEP 2141.02)**

1. The difference between the instant application and Morisawa et al. is that Morisawa et al. do not expressly teach the osmotic pressure of the salt solution or the concentration of the sodium, potassium and chloride components. This deficiency in Morisawa et al. is cured by the teachings of Cantoro (EP 0698388 A1) and Hoshino et al. (JP2000-157977).

**Finding of prima facie obviousness**

**Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of Morisawa et al. to produce an artificial salt solution of 280 to 305 mOsm/L with the instantly claimed amounts of potassium, sodium (potassium ion: sodium ions = 1:4 to 1:8) and chloride, as suggested by Cantoro and Hoshino et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Cantoro and Hoshino et al. provide guidance on the proper osmotic pressure to use in biocompatible artificial salt solutions and also provide guidance on the amounts of ions to use in such solutions. It is then merely routine optimization of the amounts of ions taught in the art to use in the method of Morisawa et al. to produce the artificial salt

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solution at the instantly claimed amounts of potassium ion: sodium ions = 1:4 to 1:8, and physical properties of the resulting solution. The amount of a specific ingredient in a composition, such as the potassium ions and sodium ions, is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. The predictable expected result is a salt solution.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Response to arguments:**

Applicant asserts that Morisawa reference does not suggest cleaning the eyes or nose. However, with respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, **used as a cleaning solution for eyes or the nose**, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 6 of copending Application No. 12/165215. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or is embraced by the subject matter of the copending application. Copending 12/165215 discloses:

1. (currently amended) An artificial physiological salt solution which can be used as a cell culture solution for a primary culture cell, wherein  
the active hydrogen reaction value is 0.1 to 1,  
the pH is 6.9 to 7.5, and 7.5 and  
the osmotic pressure is 260 mOsm/L. to 310 mOsm/L.,  
wherein said artificial physiological salt solution comprises and including  
115 mEq/L. to 155 mEq/L. of sodium ions,  
1 mEq/L. to 8 mEq/L. of potassium ions, and  
80 mEq/L. to 120 mEq/L. of chloride ions, and  
wherein adjustment of the ion balance is carried out in electrolytic reduction water.

The copending application does not expressly teach an intended use as a cleaning solution for the eyes or the nose.

However, one of ordinary skill in the art would recognize the intended use as being intrinsic to the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/  
Examiner, Art Unit 1616